

**K160124 LUMIS Cannulated Pedicle Screw Fixation System,  
U.L.I.S. Pedicle Screw Fixation System**

Apr 4, 2016  
75 days to decision

K160124 · Product code: MNI · Orthopedic  
Source: <https://www.510kdatabase.net/k160124/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jan 20, 2016
Decision date	Apr 4, 2016
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinevision S.A.</b>
Location	Douglasville, PA, US
Contact	Helene Plas
510(k) history	5 submissions · 5 cleared · 2012-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k160124/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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